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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/554,732	01/05/2007	Christian Hubschwerlen	64391(41925)	9693

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EXAMINER	
ZAREK, PAUL E	

ART UNIT	PAPER NUMBER
1628	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/554,732	HUBSCHWERLEN ET AL.	
	Examiner	Art Unit	
	Paul Zarek	1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 August 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *54-68* is/are pending in the application.

4a) Of the above claim(s) *54-66* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *67 and 68* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/20/2009, 02/05/2010, 08/18/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 54-68 have been added, and Claims 25-53 have been cancelled by the Applicant in correspondence filed on 08/18/2010. Claims 54-68 are currently pending. This is the second Office Action on the merits of the claim(s).

2. Newly submitted claims 54-66 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: these claims are drawn to a compound or composition of Formula (II) whereas the elected invention was drawn to a method of treating infection. Had the compound/composition claims been presented initially, they would have been restricted. These are different statutory categories.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, Claims 54-66 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. Claims 67 and 68 are examined herein.

RESPONSE TO ARGUMENTS

3. Claims 28 and 53 were objected to. These objections are moot in light of Applicants' cancellation of the Claims.

4. Claims 28-32, 34-38, 40-43, and 48-53 were rejected under 35 U.S.C. 112, first paragraph. These rejections are moot in light of Applicants' cancellation of the Claims.

5. Claims 28-32, 34-38, 40-43, and 45-53 are rejected under 35 U.S.C. 112, second paragraph. These rejections are moot in light of Applicants' cancellation of the Claims.

6. Claims 28-32, 34-38, 40-43, and 45-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gordeev, et al. (International Application No. WO 02/059116). These rejections are moot in light of Applicants' cancellation of the Claims.

7. Claims 28-32, 34-38, 40-43, and 45-53 were rejected under 35 U.S.C. 103(a) as being obvious over Locher (US PreGrant Publication No. 2004/0132764, which claims priority to US provisional application 60/420,810, filed on 10/23/2002) in view of Hubschwerlen and Specklin (US PreGrant Publication No. 2005/0096343, which claims priority to US provisional application 60/327,162, filed on 10/2001). These rejections are moot in light of Applicants' cancellation of the Claims.

8. Newly added Claims 67 and 68 are examined on their merits and the following **FINAL** rejection is made.

Claim Rejections - 35 USC § 112 (1st paragraph)

9. The text of Title 35, U.S.C. § 112, first paragraph, can be found in a prior Office action.

10. Claims 67 and 68 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating Gram positive infections, does not reasonably provide enablement for treating all bacterial infections or preventing any infections. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The

Wands factors were discussed in Office Action mailed on 12/19/2008. Examiner notes that "treating" is defined as "reversing, alleviating, inhibiting the progress of, or preventing the disorder or condition to which the term applies." (pg 23, lines 22-27) The instant specification does not limit the infectious agent; rather, it discloses a list of potential infectious agents (pgs 23-25). This list is not exclusive. Other infections not listed in the specification are could reasonably be interpreted to as an infection (influenza virus or plasmodium). Therefore, any infection by any organism (i.e. by virus, bacteria, fungus, or parasite) is encompassed by Claim 67. Hybrid molecules structurally related to those claimed to treat anthrax are known to be effective against Gram positive bacteria (See, Gordeev, et al. [International Application No. WO 02/059116, already of record], and Hubschwerlen and Specklin [US PreGrant Publication No. 2005/0096343, already of record]). Petri (Chapter 44 Antimicrobial Agents) and Chambers (Chapter 47 Antimicrobial Agents) (both from Goodman & Gilman's The Pharmacological Basis of Therapeutics, 10th ed., 2001, already of record) teach that quinolone and oxazolidinone are known and effective antibiotics. According to the CDC, the only known prevention method of anthrax is by vaccination. Applicants have only demonstrated that the compounds of the instant invention are effective against *B. anthracis* (pg 86, lines 12-13). Neither the instant specification nor the state of the art at the time of filing indicates that a single compound is effective for treating all other bacterial infections, or preventing any infections.

Claim Rejections - 35 USC § 103

10. The text of Title 35, U.S.C. § 103(a) can be found in a prior Office action.

11. Claims 67 and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gordeev, et al. (International Application No. WO 02/059116, already of record).

12. Claim 67 is drawn to a method of treating bacterial infections in a subject comprising administration of a compound of Formula (II). Claim 68 is drawn to a method of treating an anthrax infection in a subject comprising administration of a compound of Fromula (II).

13. Gordeev, et al., were described previously. Briefly, Gordeev, et al., disclose three preferred hybrid antibiotics in which a quinolone and oxazolidinone are chemically linked and are effective against various Gram positive bacteria. Gordeev, et al., also teach the preferred compounds as part of a pharmaceutical composition, comprising a carrier or diluent (pg 25, lines 5-21). Finally, Gordeev, et al., discuss using the disclosed compound to treat humans or other mammals (pg 27, lines 6-16). Gordeev, et al., do not disclose the elected species, the effect of the hybrid antibiotics on *B. anthracis* (which causes anthrax), or treating an animal with anthrax. Gordeev, et al., demonstrate that the linker moiety does not affect the antibacterial properties of the hybrid antibiotic. Given that the novelty of the utilized compounds resides in the linker region, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use the instantly claimed compounds to treat anthrax.

14. Examiner acknowledges Applicants' data in the reply filed on 08/18/2010. However, the arguments described therein are not persuasive. Firstly, Applicants' argument regarding the lack of motivation to incorporate the polar -OR^7 group into the compounds of Gordeev, et al. This is not persuasive because the claims are not drawn to a compound; rather, they are drawn to using the compounds of Formula (II). Given the identity and utility of the compounds of Gordeev, et al., one of ordinary skill in the art would reasonably predict that the compounds of Formula (II) are effective antibiotics against Gram positive bacteria. Secondly, the data disclosed therein are not presented in the form of a declaration and are thus interpreted as argument. Moreover, even

if the data contained therein were presented in the form of a declaration, Applicants' have not conclusively demonstrated that the instantly claimed method is superior over Gordeev, et al. The solubility data of Table 1 shows that one compound of the instant scope is 28 times more soluble than a compound of Gordeev, et al. This data does not indicate that all or a representative number of compounds of Formula (II) possess the enhanced, unexpected solubility. Furthermore, Table 2 demonstrates that compounds of Formula (II) (Examples 72, 76, 79, 83, 84, 86, and 87) are equally effective against various bacteria compared to the compounds of the prior art. Thus, the compounds used in Claim 67 are not unexpectedly superior to those of the prior art with respect to antibacterial properties.

15. Claims 67 and 68 are rejected under 35 U.S.C. 103(a) as being obvious over Locher (US PreGrant Publication No. 2004/0132764, which claims priority to US provisional application 60/420,810, filed on 10/23/2002, already of record) in view of Hubschwerlen and Specklin (US PreGrant Publication No. 2005/0096343, which claims priority to US provisional application 60/327,162, filed on 10/2001, already of record).

The applied reference has a common inventor and assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR

1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

10. Locher and Hubschwerlen and Specklin were discussed previously. Briefly, this combination of prior art teaches numerous compounds that possess the same quinolone and oxazolidinone derivatives as the elected species. The only differences being the identity of the linker moiety. The prior art discloses so many variations of these molecules that one of ordinary skill in the art would reasonably expect that the elected species would be an effective treatment for anthrax, which is caused by another Gram-positive bacteria, *B. anthracis*. Therefore it would have been *prima facie* obvious to use the elected compound to treat subjects suffering from anthrax, or an infection by *B. anthracis*, which can cause anthrax.

16. Applicants' arguments regarding motivation to add the polar -OR^7 group and alleged solubility are discussed above and are not found persuasive.

Conclusion

17. Newly added Claims 67 and 68 are rejected.

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Zarek whose telephone number is (571) 270-5754. The examiner can normally be reached on Monday-Thursday, 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brandon Fetterolf can be reached on (571) 272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PEZ

/San-ming Hui/
Primary Examiner, Art Unit 1628